

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Substitute for form 1449/PTO, based on PTO/SB/08A and 08B	Application Number	10/616,692
		Filing Date	07/09/2003
		First Named Inventor	NELSON, Jodi
		Art Unit	1614
		Examiner Name	Royds, Leslie A.
		Attorney Docket Number	47-00B

Confirmation No. 1639

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**U.S. PATENT DOCUMENTS**

Examiner Initial*	Cite No.	Patent Number	Issue Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	5,314,894	05/24/1994	Stecher et al.	

**U.S. PATENT APPLICATION PUBLICATIONS**

Examiner Initial*	Cite No.	Publication Number	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear

**FOREIGN PATENT DOCUMENTS**

Examiner Initial*	Cite No.	Foreign Document Number	Country Code	Publication Date (MM-DD-YYYY)	Name	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
	2	WO 01/03649	WO	01/18/2001	Nelson		

**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initial*	Cite No.	REFERENCE Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
	3	ABBOTT, N.J. et al., "Transporting therapeutics across the blood-brain barrier" Molecular Medicine Today, March 1996, Vol. 2, Issue 3, pp. 106 – 113	
	4	"ARALEN® CHLOROQUINE PHOSPHATE, USP" (2001), Aralen® package insert text downloaded November 13, 2007 from <a href="http://www.fda.gov/cder/foi/label/2003/06002slr039_aralen_lbl.pdf">www.fda.gov/cder/foi/label/2003/06002slr039_aralen_lbl.pdf</a> , pgs. 4,26.	
	5	BRANSKI et al., "Effect of Cimetidine on Human Gastric and Duodenal Prostanoid Synthesis," Scand J Gastroenterol, 1984, 19(4), pp.457-460.	
	6	"Carbidopa/levodopa" Micromedex Healthcare Series, <a href="http://micromedex.uchsc.edu/mdxcgi/quiklocln.exe?CT">http://micromedex.uchsc.edu/mdxcgi/quiklocln.exe?CT</a>	
	7	Chloroquine downloaded from the Inchem database of the International Programme on Chemical Safety (IPCS), at <a href="http://www.inchem.org/documents/pims/pharm/chloroqu.htm">http://www.inchem.org/documents/pims/pharm/chloroqu.htm</a> . Pgs. 1, 7 and 9.	

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	8	CHLOROQUINE downloaded from the MICROMEDEX® Interactions Table on July 24, 2008.	
	9	EINARSON, T. R. et al. (1985) "Gout-like arthritis following cimetidine and ranitidine", Drug Intell. Clin. Pharm 19(3):201-202	
	10	ETTE, E.I. et al. (1987), "Chloroquine Elimination in Humans: Effect of Low-Dose Cimetidine," J. Clin. Pharmacol. 27:813-816.	
	11	FINK et al., "Chloroquin-Enantiomere," 1979, pp.163-164.	
	12	GOTO, M. et al. (2001), "Intra-articular injection of hyaluronate (SI-6601D) improves joint pain and synovial fluid prostaglandin E2 levels in rheumatoid arthritis: A multicenter clinical trial," Clin. And Exp. Rheumatol. 19:377-383	
	13	"Guidance for Industry" (November 1999), downloaded from FDA website, pg.13	
	14	HABERKORN et al., "Antimalarial Activity in Animals of the Optical Isomers of Chloroquine Diphosphate," Tropenmed. Parasit. 1979, 31, pp.308-312.	
	15	"Histamine H <sub>2</sub> Antagonists," Drug Facts & Comparisons, Mar 2002, pp.1129-1130.	
	16	IREDALE et al., "CHARACTERISTICS OF HYDROXYCHLOROQUINE: Determination of the Stereoisomers of Hydroxychloroquine and Its Major Metabolites in Plasma and Urine Following a Single Oral Administration of Racemic Hydroxychloroquine," Seminar in Arthritis and Rheumatism, 1993, 23, pp.74-81.	
	17	KHONG, T.K. and Rooney, P.J. (1980), "Arthritis Associated with Cimetidine," Lancet 2:9208-8209):1380.	
	18	MANGER, B.F. et al. (1983) "Cimetidine and psoriatic arthritis" Arch. Dermatol. 119(10)792.	
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	20	MINE et al., "Healing of Chronic Gastric Ulcer Depends on Gastric Mucosal Prostaglandin Synthesis," Hepato-Gastroenterol, 1994, 41, pp.111-115.	
	21	MUSTAPHA et al., "Effects of cimetidine on the absorption kinetics of chloroquine," African Journal of Pharmacy & Pharmaceutical Sciences, 1993, 23(1), pp.51-54.	

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	22	NIVAQUINE ® downloaded from MEDSAFE , New Zealand Medicines and Medical Devices Safety Authority, a business unit of the Ministry of Health, at <a href="http://www.medsafe.govt.nz/profs/Datasheet/n/Nivaquininetabsyr.htm">http://www.medsafe.govt.nz/profs/Datasheet/n/Nivaquininetabsyr.htm</a> .	
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	25	PACIFICI, G.M. et al. (1992), "Histamine N-methyl transferase:inhibition by drugs," Br. J. Clin. Pharmac. 34(4):322-327.	
	26	Physician's Desk Reference for the year 2000, entry for Aralen®, pp. 2734-2735	
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	28	ROBINSON et al., "Prostaglandin-Stimulated Bone Resorption by Rheumatoid Synovia," The Journal of Clinical Investigation, 56, 1975, pp.1181-1188.	
	29	SHARON et al., "Prostanoid Synthesis by Cultured Gastric and Duodenal Mucosa: Possible Role in the Pathogenesis of Duodenal Ulcer," Scan J Gastroenterol, 1983, 18, pp.1045-1049.	
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	32	STOCKLEY, Ivan H. (1999) "Drug Interactions, A Source Book of Adverse Interactions, Their Mechanisms, Clinical Importance and Management" 5 <sup>th</sup> Ed., pg.131.	
	33	SUGIYAMA et al., "Interleukin-4 inhibits protaglaglandin E <sub>2</sub> production by freshly prepared adherent rheumatoid synovial cells via inhibition of biosynthesis and gene expression of cyclo-oxygenase II but not of cyclo-oxygenase I," Annals of the Rheumatic Diseases, 1996, 55, pp.375-382.	

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	34	TETT et al., "A dose ranging study of the pharmacokinetics of hydroxy-chloroquine following intravenous administration to healthy volunteers," Br. J. Clin. Pharmac., 1988, 26, pp.303-313.	
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	36	WISELOGLE, ed., "A Survey of Antimalarial Drugs," 1946, 1, pp.388-390.	
	37	YAMAUCHI, K., et al. (1994) "Structure and function of human histamine N-methyltransferase: critical enzyme in histamine metabolism in airway," Am. J. Physiol. Lung Cell Mol. Physiol 267:L342-L349.	
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